

Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 21, 1995, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of SAFHS® represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for SAFHS® is 3,073 days. Of this time, 1,532 days occurred during the testing phase of the regulatory review period, while 1,541 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun:* May 9, 1986. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)) for human tests to begin became effective on May 9, 1986.

2. *The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e):* July 18, 1990. FDA has verified the applicant's claim that the premarket approval application (PMA) for SAFHS® (PMA P90009) was initially submitted on July 18, 1990.

3. *The date the application was approved:* October 5, 1994. FDA has verified the applicant's claim that PMA P90009 was approved on October 5, 1994.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,825 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 23, 1995, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before October 23, 1995, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42,

1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 17, 1995.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 95-10076 Filed 4-21-95; 8:45 am]

BILLING CODE 4160-01-F

Health Resources and Services Administration

Availability of Funds for the Provision of Technical and Nonfinancial Assistance to Federally Funded Migrant Health Centers and Related Organizations

AGENCY: Health Resources and Services Administration, PHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration announces the availability of approximately \$1.4 million in fiscal year (FY) 1995, to support a total of four grants under Section 329(g)(1) of the Public Health Service (PHS) Act for the provision of technical and nonfinancial assistance to migrant health centers (MHCs).

The above technical assistance includes the following activities:

(1) Assist MHCs by the development of cost effective vision screening and treatment tools (e.g. health education and training materials, focometer), as well as, optometric technical assistance to MHCs (e.g. assistance request form, needs assessment, planning, training of providers and identification of community and regional resources).

(2) Recruit, train and place, seasonal bilingual and culturally sensitive health (e.g., MDs, ODs, mid-levels) and allied health professionals (e.g., nutritionist, social worker, health educator and community service worker) at East Coast MHCs to perform outreach duties.

(3) Provide technical assistance to MHCs nationwide to develop farmworker peer counseling and outreach programs; including the recruitment, training and placement of peer counselors, and program planning and identification of resources.

(4) Recruit, train and place bilingual outreach teams (e.g., nurse practitioner/

nurse, health educator/community outreach worker) in Florida that specifically target farmworker infants, children and youth up to 21 years of age not currently receiving health care services. The teams are to work with MHCs and other organizations serving farmworkers. Other activities of this grant are to assist in State and local strategic planning to increase farmworker access to MHCs and health services.

The four grants will be awarded with a budget period of one year and a project period of up to three years.

The objective of these activities is to improve access to preventive and primary care services for underserved populations, especially minority and other disadvantaged populations. This is in keeping with the health promotion and disease prevention objectives of Healthy People 2000, and also the objectives defined specifically for the farmworker population in the PHS publication Migrant and Seasonal Farmworker (MSFW) Health Objectives for the Year 2000. Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No.017-001-00474-0 or Healthy People 2000 (Summary Report: Stock No. 017-00473-01) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (Telephone 202-783-3228). Potential applicants may obtain a copy of MSFW Objectives for the Year 2000 through the National Migrant Resource Program, Inc., 1515 Capital of Texas Highway South, Suite 220, Austin, Texas 78746 (Telephone 1-800-531-5120).

Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities in which education, library, day care, regular and routine health care and early childhood development services are provided to children. Smoking must also be prohibited in indoor facilities that are constructed, operated or maintained with Federal funds.

DATES: Applications are due June 8, 1995. Applications shall be considered as meeting the deadline date if they are either: (1) received on or before the deadline date; or (2) postmarked on or before the deadline date and received in time for orderly processing. A legibly dated receipt from a commercial carrier or the U.S. Postal Service will be accepted in lieu of a postmark. Private metered postmarks will not be acceptable proof of timely mailing. Applications which do not meet the deadline will be considered late and will be returned to the applicant.

ADDRESSES: Application materials (PHS Form 5161-1 with revised face sheet DHHS Form 424, as approved by the Office of Management and Budget (OMB) under control number 0937-0189) may be obtained from the Bureau of Primary Health Care (BPHC), Office of Grants Management, Nancy Benson, (301) 594-4260, 4350 East-West Highway, 11th Floor, Bethesda, MD 20814. Ms. Benson is available for further information regarding application submission procedures and to provide assistance on business management issues. Completed applications should be mailed to: Grants Management Officer, BPHC, c/o Houston Associates, Inc., 1010 Wayne Avenue, Suite 240, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: For general program information, contact Mr. Antonio Duran, Director, or Helen Kavanagh, Migrant Health Branch, Division of Community and Migrant Health, BPHC, Health Resources and Services Administration, (301) 594-4303, 4350 East-West Highway, 7th Floor, Bethesda, MD 20814.

SUPPLEMENTARY INFORMATION:

Background

There are 106 MHCs which provide comprehensive primary health care to migrant and seasonal farmworkers and their families in their home base or as they work along one of the three migrant streams. The technical and nonfinancial assistance will be arranged for or provided within available resources by four separate grantees in response to MHC requests for: (1) vision screening and treatment services, (2) bilingual seasonal outreach staff, (3) peer counselor training and outreach, and (4) outreach staff specializing in identifying children and youth who fall through the "cracks" of health care services.

Legislation governing these activities can be found at section 329 of the PHS Act. Paragraph (1)(B) of section 329(a) requires that a migrant health center provide "as may be appropriate for particular centers, supplemental health services necessary for the adequate support of primary health services," and paragraph (1)(G) requires that a migrant health center provide "information on the availability and proper use of health services and services which promote and facilitate optimal use of health services, including if a substantial number of the individuals in the population served by a center are of limited English-speaking ability, the services of appropriate personnel fluent in the language spoken by a

predominant number of such individuals".

Number and Amount of Awards

Each individual and/or organization is limited to submitting a maximum of one grant proposal for any one of the four activities mentioned. A maximum of 4 separate grants will be awarded for: optometric technical assistance for MHCs nationwide (approximately \$45,000); the recruitment, training and placement of outreach allied health and health professionals with MHCs on the East Coast (approximately \$800,000); the development, implementation and promotion of farmworker peer counselor programs at MHCs nationwide (approximately \$225,000); and the enhancement of farmworker outreach health care services targeting infants, children and youth at MHCs in Florida, in addition, to State and local strategic planning (approximately \$320,000).

Eligible Applicants

Eligible applicants are public and private nonprofit entities with culturally competent and diverse staff which have demonstrated experience, as appropriate to the requested grant, in optometric technical assistance for MHCs; farmworker outreach; the recruitment, training and placement of health and allied health professionals at MHCs; or in farmworker peer counselor recruitment, training and placement.

Criteria for Evaluation

Regulations governing these awards provide that the Secretary will award funds to applicants which, in her judgment, will best promote the purposes of the statute, taking into consideration (a) the cost effectiveness of the application, and (b) the number of centers and entities to be served by the applicant. 42 CFR 56.704. In addition to these two criteria, the Secretary, in considering what will best promote the purposes of the statute, will consider:

- (1) The extent to which the applicant's program activity demonstrates and addresses the particular needs of the migrant and seasonal farmworkers and migrant health centers;
- (2) The degree to which the applicant addresses the overall goals and objectives of one of the aforementioned activities;
- (3) The appropriateness and adequacy of the methodology which describes how the activity will be evaluated, along with relevant timeliness;
- (4) The information contained in annual progress reports (for existing grantees only);

(5) The extent to which the project plan describes activities in measurable terms;

(6) The extent of the organization's prior related and applicable experience (to be documented by a short synopsis of work completed for each Federal and non-Federal grant received, contact person(s) and phone number(s)); and

(7) The degree to which the fiscal and administrative management systems, and the budget are well organized, detailed, justified and consistent with the project plan.

All applications for the technical and nonfinancial assistance to MHCs will be reviewed competitively by a PHS Objective Review Committee.

Other Award Information

The grants awarded under this notice are not subject to the provisions of Executive Order 12372 or the Public Health System Reporting Requirements.

In the OMB Catalog of Federal Domestic Assistance, the Migrant Health Center program is Number 93.129.

Dated: April 14, 1995.

Ciro V. Sumaya,
Administrator.

[FR Doc. 95-10019 Filed 4-21-95; 8:45 am]

BILLING CODE 4160-15-P

Health Resources Services Administration

Availability of Funds for Grants To Build Primary Health Care Capacity in the Pacific Basin

AGENCY: Health Resources and Services Administration, PHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces the availability of approximately \$1.3 million in fiscal year (FY) 1995 for competing applications for the Pacific Basin Health Initiative. This Initiative supports the development of primary health care infrastructure in the Pacific Basin, and funds will be awarded under the authority of section 301 of the Public Health Service (PHS) Act. The overall goal of the program is to achieve the effective delivery of comprehensive primary health care services and to encourage community responsibility for health promotion and disease prevention. The six Pacific jurisdictions affected by this initiative are the three flag territories (the Commonwealth of the Northern Mariana Islands, American Samoa, and Guam), and the three sovereign nations whose relationships with the U.S. are governed by Compacts